

**Application No.: 10/519,338**  
**Filing Date: September 19, 2005**

## **REMARKS**

The remarks herein are responsive to the Final Office Action dated 15 June 2009. Upon entry of the foregoing amendments, Claims 8-25, 29-36, 42, 43, 45, and 46 remain pending. Claims 8, 33, and 43 have been amended. No new claims have been added. Claims 1-7, 26-28, 37-41, and 44 have been canceled without prejudice and Applicant reserves the right to pursue the subject matter in the canceled claims at a later date.

Additionally, Applicant thanks the Examiner for her time and comments during the Examiner interview of 3 September 2009.

### **Response to Arguments**

In response to Applicants' previous arguments, the Office Action first argues that the evidence presented is insufficient to outweigh the evidence of obviousness. Applicant respectfully disagrees and traverses this finding. After considering the evidence insufficient, the Office Action generally argued that the "pits" of Steinemann are not contrary to the open pores of references such as Pilliar. Instead, the Office Action argued that the "porous surface" of Steinemann is equivalent to the open pores of Pilliar. Applicant respectfully disagrees and traverses the rejections, but nevertheless has amended the claims to expedite prosecution. Supplementary to arguments below regarding those amendments, Applicant now provides the following responses to previous arguments to expedite allowance of the pending claims.

Applicant understands that the general issues below have been previously discussed. However, Applicant respectfully maintains the position that the combination is improper. Further, Applicant submits that the arguments below provide reasons for said position beyond those previously presented to the Examiner.

### ***Pits, Pores, and Microroughness***

To clarify the argument, Applicant first analyzes use of the terms "pits," "porous," and "microroughness" in Steinemann. In Steinemann "pits" usually refers to features produced by the reducing acid. However, sandblasting a surface also clearly produces pits. **Thus, the term "pits" cannot distinguish the acid pits from the sandblasted pits of Steinemann.**

**Regarding “pores” and “microroughness,” both terms are used interchangeably, and describe both the acid pits and the sandblasted pits.** Beginning with “microroughness,” Claim 1 of Steinemann states that the “reducing acid [provides a] microroughness.” However, Claim 6 states that “a fine pitting [presumably produced by the reducing acid] is superimposed on the microroughness,” this microroughness presumably being sandblasted pits. Steinemann’s dual-meaning of “microroughness” is highlighted at col. 3 line 67 through col. 4 line 5, where “microroughness” separately describes both the acid-produced fine pitting and the sandblasted pits in a single sentence.

The term “porous” is used rarely in Steinemann, but its most reasonable interpretation also encompasses both types of pits. Steinemann does not appear to claim any structures that could be “porous” other than pits. Both the acid and the sand blasting produce pits, and the related “microroughness” term is used to describe both of these pits interchangeably. Thus, “porous” also refers to both pits. As an example, Claim 6 recites “a **porous** metallic biocompatible surface... is provided with micro-roughness and a fine pitting is superimposed on the micro-roughness.” Clearly, both the “provided” and “superimposed” features create the “porous” aspect of the surface.

Further review shows that the **acid pits** provide the only “porous” features of importance according to Steinemann. As stated:

“The improvements were unquestionably related to the **main feature of the invention**, namely, that the contact surface was provided with a micro-roughness having an  $R_t$  greater than 10  $\mu\text{m}$  and an RS less than 10  $\mu\text{m}$ . This micro-roughness was produced by means of an acid treatment using a reducing acid. **This operation alone produced the results desired** by effectively pitting the surface of the metallic surface to be implanted. Sandblasting may be used, however, as a step preceding the reducing acid treatment.” Steinemann at 3:38-46

Thus, Steinemann teaches that the acid pits alone are sufficient to produce the desired results, and the sandblasted pits are a mere afterthought.

**In fact, it’s not clear from Steinemann that sandblasting has any effect on the final product.** For example, the paragraph cited above later states that the “ $R_t$  [is] larger than 10  $\mu\text{m}$  as impressed by the sandblasted grain;” but earlier in that paragraph Steinemann states that the same result is achieved by the acid alone. Applicant submits that the same result likely occurs,

with or without sandblasting, because the acid destroys the sandblasted pits.<sup>1</sup> Thus, Steinemann's disclosure of any surface with two layers of structure is questionable, since the acid can produce the same results alone. Thus, it is also questionable whether the sandblasted pits actually form any aspect of the "porous surface."

One must consider the tenuous significance of the sandblasted pits when reading Steinemann's comparisons with the prior art. If the sandblasted pits had any effect or if the sandblasted pits were similar to the larger pores in references such as Pilliar (as implied by the Office Action), then Steinemann's results would not stand "in perfect contrast to opinions expressed so far in literature." (Steinemann at 6:30-31)

Steinemann's description of this result as being "in perfect contrast" with the prior art highlights the lack of motivation at the time to combine such references. Alluding to a motivation to combine, the Office Action argues that "[i]t is very well known in the art that pores must be greater than about 100 microns for [bone to grow into the implant]." Applicant respectfully submits that this indicates hindsight bias, as the cited references do not demonstrate an understanding of the distinct bonding mechanisms of an open-pored structure and a microroughness. The importance of bone ingrowth (as distinct from bone ongrowth) may be well known in the art now, but it has not been shown to be known at the time of the invention. In the previously filed declaration (Declaration of Vinzenz Max Frauchiger, filed 9 April 2009) Applicant presented evidence that this was not understood at the time of the invention. The conclusory statement that this was "very well known" does not overcome the evidence presented, and does not substantiate a finding of obviousness.

In summary, Applicant submits that Steinemann teaches a "porous surface" including only pits, and not the open-pores claimed. Further, it is questionable whether the surface produced by Steinemann includes more than one level of pit-structure, as the acid treatment alone produces the same results. Steinemann teaches that only its fine pitting is important, and thus does not teach the value of fine-pitting over another porous surface. Finally, Steinemann indicates that its method is "in perfect contrast" with prior art teaching larger pore sizes. For these reasons, Applicant submits that the combinations including Steinemann are improper.

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<sup>1</sup> Applicant again argues that the acid treatment of Steinemann would destroy the surfaces of Pilliar, etc., for similar reasons.

***Vacuum Plasma Spraying***

As discussed during the interview, Applicant submits that Steinemann also teaches away from vacuum plasma spraying. “[One] object of [Steinemann’s] invention relates to an implant of the aforementioned kind in which the improved surface texture is formed directly in the metal mass on the outer periphery of the contact surface, rather than on a brittle plasma coating to be separately applied thereunto.” (Steinemann at 2:56-61) Steinemann teaches away from plasma coats, arguing “that the mechanically brittle plasma layer has a tendency to break or peel off.” (Steinemann at 2:4-5). Moreover, the stated objective in Steinemann is to provide an implant “which is not associated with the drawbacks and limitations of the prior art,” one of which is the belief that “the mechanically brittle plasma layer has a tendency to break or peel off.” (Steinemann at 2:39-42; 2: 4-5).

The Office Action argues that “Steinemann is referring to a process for creating a roughness by [plasma coating] and not an open-pored porosity.” First, Applicant submits that the validity of this distinction is irrelevant. If a reference teaches that a layer “has a tendency to break or peel off,” then such a layer would not be used by a person having ordinary skill in the art that trusts that reference. A layer that peels off loses its connection with the bone – an unacceptable result in the field of the invention. Thus, Steinemann teaches away from a plasma coating for either layer.

Second, Applicant respectfully submits that Steinemann appears to discuss plasma coating in relation to a larger surface structure, as opposed to the smaller structure associated with the “fine pitting.” However, as Steinemann teaches away from the plasma coating in either case, Applicant submits that this issue is moot.

**Rejections of Claims Under 35 U.S.C. § 103**

***Claims 1, 2, 4-7, 26-28, 37-40, 41, and 44***

Claims 1, 2, 4-7, 26-28, 37-40, 41, and 44 stand rejected under 35 U.S.C. § 103 as being unpatentable over Steinemann (U.S. Pat. No. 5,456,723) in combination with one or more of Pilliar (U.S. Pat. No. 3,855,638), Shimamune (U.S. Pat. No. 5,034,186), Landry (U.S. Pat. Pub. 2004/0030387), and Rowe (U.S. Pat. No. 4,542,539). The subject matter of each reference has

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been discussed in previous communications. Applicant has canceled claims 1-7, 26-28, 37-41 and 44 without prejudice.

As discussed above, Applicant respectfully submits that the combination of Steinemann with the other references to show a surface with open-pores and a surface micro-structure, among other limitations in the claims, is inappropriate.

Claims 37-40 and 44 also recite, *inter alia*, “wherein at least one of the open-pored implant surface and the surface micro-structure are applied to the implant via a vacuum plasma spraying method.” Applicant respectfully submits that Steinemann teaches away from the use of a vacuum plasma spraying method in either case, as discussed above.

Nevertheless, Applicant has canceled the claims to expedite allowance of the remaining claims. Applicant reserves the right to pursue the subject matter of these claims in the future, such as in a continuing application.

*Claims 8-25, 29-32, 42, and 45*

Claims 8-25, 29-32, 42, and 45 stand rejected under 35 U.S.C. § 103 as being unpatentable over Steinemann in combination with one or more of Pilliar, Shimamune, Landry, Rowe, and “Pilliar2” (U.S. Pat. No. 4,206,516). The subject matter of each reference has been discussed in previous communications.

As discussed above, Applicant respectfully submits that the combination of Steinemann with the other references to show a surface with open-pores and a surface micro-structure, among other limitations in the claims, is inappropriate. Nevertheless, Applicant has amended the claims to further distinguish the prior art cited.

Amended Claim 8 now recites, *inter alia*, “producing a surface micro-structure on the open-pored structure by a vacuum plasma spraying method.” To the extent that Steinemann’s criticism of plasma coatings applies to the acid pit roughness, Applicant respectfully submits that Steinemann teaches away from the amended claim, as discussed above.

For at least the reasons described above and in previous communications, Applicants submit that Claims 8 is allowable over Steinemann in view of Pilliar, Shimamune, Landry, Rowe, and/or Pilliar2. Claims 9-25, 29-32, 42, and 45 depend from independent Claim 8 and are therefore likewise allowable over the cited references, not only because they depend from an

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allowable base claim, but also because each of these claims recites a unique combination of features, not taught or suggested by the cited art.

*Claims 33-36, 43, and 46*

Claims 33-36, 43, and 46 stand rejected under 35 U.S.C. § 103 as being unpatentable over Steinemann in view of one or more of Landry and Rowe. The subject matter of each reference has been discussed in previous communications.

As discussed above, Applicant respectfully submits that the combination of Steinemann with the other references to show a surface with open-pores and a surface micro-structure, among other limitations in the claims, is inappropriate.

Claim 33 also recites, *inter alia*, “wherein the open-pored implant surface is produced by a vacuum plasma spraying method.” To the extent that Steinemann’s criticism of plasma coatings applies to a “porous surface” (as used in Steinemann or otherwise), Applicant respectfully submits that Steinemann teaches away from the amended claim, as discussed above.

For at least the reasons described above and in previous communications, Applicants submit that Claims 33 is allowable over Steinemann in view of Landry and/or Rowe. Claims 34-36, 43, and 46 depend from independent Claim 33 and are therefore likewise allowable over the cited references, not only because they depend from an allowable base claim, but also because each of these claims recites a unique combination of features, not taught or suggested by the cited art.

*No Disclaimers or Disavowals*

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not

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reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

**Co-Pending Applications of Assignee**

Applicants wish to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

<b>Serial Number</b>	<b>Title</b>	<b>Filed</b>
11/722,697	A METHOD OF SURFACE FINISHING A BONE IMPLANT	12/22/2005
12/092,545	OPEN-PORE BIOCOMPATIBLE SURFACE LAYER FOR AN IMPLANT, METHODS OF PRODUCTION AND USE	5/2/2008

**CONCLUSION**

For at least the forgoing reasons, the Applicants believes that Claims 1-2 and 4-46 are allowable over the art of record and are in condition for immediate allowance.

The Applicants respectfully submit that any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion or that the limitation discussed is essential or critical; rather, patentability must rest on each claim taken as a whole. The Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although changes to the claims have been made, no acquiescence, disclaimer or estoppel is intended or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. The Applicants may not have presented in all cases, all arguments concerning whether the applied references can be properly combined or modified in view of the deficiencies noted above, and Applicants reserve the right to later contest whether the cited references can be properly combined or modified.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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